REMARKS

The Office Action mailed September 14, 2010 has been received and reviewed. Each of claims 1, 3, 5-8, 10, 12-15, 17 and 19-23 stands rejected. Claims 1, 8 and 15 have been amended herein. The support for these amendments can be found in the specification at paragraphs [0053]-[0055] and FIG. 5. Care has been exercised to introduce no new subject matter. Reconsideration of the above-identified application in view of the above amendments and the following remarks is respectfully requested.

Rejections based on 35 U.S.C. § 103

Title 35 U.S.C. § 103(a) declares that a patent shall not issue when "the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." In *Graham v. John Deere,* the Supreme Court counseled that an obviousness determination is made by identifying: the scope and content of the prior art; the level of ordinary skill in the prior art; the differences between the claimed invention and prior art references; and secondary considerations. *See Graham v. John Deere Co.*, 383 U.S. 1 (1966).

"In determining the differences between the prior art and the claims, the question under 35 U.S.C. 103 is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious." MPEP § 2141.02(I) (emphasis in original) (citing *StratoFlex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 218 USPQ 871 (Fed. Cir. 1983)). "All words in a claim must be considered in judging the

patentability of that claim against the prior art." MPEP § 2143.03 (quoting *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (C.C.P.A. 1970)). Moreover, if an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. MPEP § 2143.03 (citing *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)).

"The examiner bears the initial burden of factually supporting a *prima facie* conclusion of obviousness. If the examiner does not produce a *prima facie* case, the applicant is under no obligation to submit evidence of nonobviousness . . . . To reach a proper determination of obviousness, the examiner must step backward in time and into the shoes worn by the hypothetical 'person of ordinary skill in the art' when the invention was unknown and just before it was made. In view of all factual information, the examiner must then determine whether the claimed invention 'as a whole' would have been obvious at that time to that person. *Id* (emphasis added). Knowledge of applicant's disclosure must be put aside in reaching this determination . . . . [I]mpermissible hindsight must be avoided and the legal conclusion must be reached on the basis of the facts gleaned from the prior art." MPEP § 2142.

"The key to supporting any rejection under 35 U.S.C. 103 is the **clear articulation of the reason(s)** why the claimed invention would have been obvious." MPEP § 2142 citing *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727 (U.S. 2007) (emphasis added), which notes that the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit. Moreover, the Federal Circuit has stated that "'rejections on obviousness **cannot be sustained with mere conclusory statements**; instead, there must be some **articulated reasoning** with some rational underpinning to support the legal conclusion of obviousness.'" MPEP § 2142 (emphasis added) (citing *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006)). See also *KSR*, 127 S. Ct. at 1741 (quoting Federal Circuit statement with approval).

Claims 1, 3, 5-8, 10, 12-15, 17 and 19-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ichikawa (Internal Medicine, July 2000, vol. 39, no. 7, pp. 523-524, hereinafter Ichikawa) in view of Reinhoff et al. (U.S. Publication No. 2002/0049772, hereinafter Reinhoff) in view of Fey et al. (U.S. Publication No. 2002/0038227, hereinafter Fey) and further in view of Fiedotin et al. (U.S. Patent No. 7,509,263, hereinafter Fiedotin) and further in view of Hogan (U.S. Publication No. 2002/0110823 with a priority date of 7/11/2000, hereinafter Hogan). As the combination of the Ichikawa, Reinhoff, Fey, Fiedotin and Hogan references fail to teach or suggest all features of the rejected claims, Applicants respectfully traverse this rejection, as hereinafter set forth.

Independent claim 1 as amended herein is generally directed to a computer-implemented method for displaying information on one or more user interfaces regarding the likelihood a person has a gene variant indicative of an atypical event. The method includes the steps of: displaying a first user interface to a clinician, the user interface configured to display and receive clinical agent information including at least one identifier of a clinical agent; receiving from the user interface the clinician's inputs including at least one identifier of a clinical agent and a dosage of the clinical agent, wherein receiving includes receiving a selection of an entry in a listing of clinical agents on the first user interface and a selection of the dosage from a range of dosages recommended for the clinical agent associated with the selected entry; accessing a data structure to determine if a gene variant is known to be associated with one or more atypical events for the identifier of the clinical agent received from the clinician, wherein the data structure includes an agent-gene association table; inquiring if the person to whom the clinical agent is to be administered has a stored genetic test result value for the gene variant, wherein inquiring includes accessing an electronic medical record (EMR) of the person;

accessing hereditary information for the person if the person does not have a genetic test result value for the genetic variant, the hereditary information being information that may be utilized to determine if the person has a predisposition for certain conditions, wherein the hereditary information is obtained from the EMR of the person; utilizing the hereditary information for the person to determine the likelihood the person has the gene variant; generating an output including information regarding the likelihood that the person has the gene variant indicative of an atypical event based on the hereditary information; displaying a second user interface to the clinician, the user interface configured to display the output regarding the likelihood the person has the gene variant indicative of an atypical event for the identifier of the clinical agent received from the clinician; determining a first risk of damage to the person, the first risk of damage being associated with administering to the person the dosage of the clinical agent as indicated by the clinician; determining a second risk of damage to the person, the second risk of damage being associated with the damage caused to the person by not administering the dosage of the clinical agent; utilizing the first risk of damage and second risk of damage determinations to generate an output including an automated clinical response containing suggestions for clinical actions to be taken by the clinician, and displaying a third user interface to the clinician, the user interface configured to display the output regarding the generated automated clinical response. *See generally, Specification* at ¶¶[0031]-[0036], [0039], [0041]-[0042], [0053]-[0055]; FIG. 3, FIG. 5, FIG. 6.

As amended herein, independent claim 8 is directed to a computer system embodied on one or more computer storage media having computer-executable instructions embodied thereon for displaying information on one or more user interfaces regarding the likelihood that the person has the gene variant indicative of an atypical event based on the

hereditary information. The system includes: a first displaying component that displays a first user interface to a clinician, the user interface configured to display and receive clinical agent information including at least one identifier of a clinical agent; a receiving component that receives from the user interface the clinician's inputs including at least one identifier of a clinical agent and a dosage of the clinical agent, wherein receiving includes receiving a selection of an entry in a listing of clinical agents on the first user interface and a selection of the dosage from a range of dosages recommended for the clinical agent associated with the selected entry; a first accessing component for accessing a data structure to determine if a gene variant is known to be associated with one or more atypical events for the identifier of the clinical agent received from the clinician, wherein the data structure includes an agent-gene association table; an inquiring component that inquires if the person to whom the clinical agent is to be administered has a stored genetic test result value for the gene variant, wherein inquiring includes accessing an electronic medical record (EMR) of the person; a second accessing component for accessing hereditary information for the person if the person does not have a genetic test result value for the gene variant, the hereditary information being information that may be utilized to determine if the person has a predisposition for certain conditions, wherein the hereditary information is obtained from the EMR of the person; a utilizing component for utilizing the hereditary information for the person to determine the likelihood the person has the gene variant; a first generating component that generates an output including information regarding the likelihood that the person has the gene variant indicative of an atypical event based on the hereditary information; a second displaying component for displaying a second user interface to the clinician, the user interface configured to display the output regarding the likelihood the person has the gene variant indicative of an atypical event for the identifier of the clinical agent received

from the clinician; a determining component for determining a first risk of damage to the person, the first risk of damage being associated with administering to the person the dosage of the clinical agent as indicated by the clinician and for determining a second risk of damage to the person, the second risk of damage being associated with the damage caused to the person by not administering the dosage of the clinical agent; a second generating component that generates and output utilizing the first risk of damage and second risk of damage determinations to generate an automated clinical response containing suggestions for clinical actions to be taken by the clinician, and a third displaying component for displaying a third user interface to the clinician, the user interface configured to display the output regarding the generated automated clinical response. *See generally, Specification* at ¶¶[0031]-[0036], [0039], [0041]-[0042], [0053]-[0055]; FIG. 3, FIG. 5, FIG. 6.

Independent claim 15 as amended herein is generally directed to a computer storage medium containing instructions for a method for controlling a computer system for displaying information on one or more user interfaces regarding the likelihood that the person has the gene variant indicative of an atypical event based on the hereditary information. The method comprising the steps of: displaying a first user interface to a clinician, the user interface configured to display and receive clinical agent information including at least one identifier of a clinical agent; receiving from the user interface the clinician's inputs including at least one identifier of a clinical agent and a dosage of the clinical agent, wherein receiving includes receiving a selection of an entry in a listing of clinical agents on the first user interface and a selection of the dosage from a range of dosages recommended for the clinical agent associated with the selected entry; accessing a data structure to determine if a gene variant is known to be associated with one or more atypical events for the identifier of the clinical agent received from

the clinician, wherein the data structure includes an agent-gene association table; inquiring if the person to whom the clinical agent is to be administered has a stored genetic test result value for the gene variant, wherein inquiring includes accessing an electronic medical record (EMR) of the person; accessing hereditary information for the person if the person does not have a genetic test result value for the genetic variant, the hereditary information being information that may be utilized to determine if the person has a predisposition for certain conditions; utilizing the hereditary information for the person to determine the likelihood the person has the gene variant; generating an output including information regarding the likelihood that the person has the gene variant indicative of an atypical event based on the hereditary information; displaying a second user interface to the clinician, the user interface configured to display the output regarding the likelihood the person has the gene variant indicative of an atypical event for the identifier of the clinical agent received from the clinician; determining a first risk of damage to the person, the first risk of damage being associated with administering to the person the dosage of the clinical agent as indicated by the clinician; determining a second risk of damage to the person, the second risk of damage being associated with the damage caused to the person by not administering the dosage of the clinical agent; utilizing the first risk of damage and second risk of damage determinations to generate an output including an automated clinical response containing suggestions for clinical actions to be taken by the clinician, and displaying a third user interface to the clinician, the user interface configured to display the output regarding the generated automated clinical response. *See generally, Specification* at ¶¶[0031]-[0036], [0039], [0041]-[0042], [0053]-[0055]; FIG. 3, FIG. 5, FIG. 6.

Independent claims 1, 8 and 15 have been amended herein to recite a clarification of the systems and methods for displaying information on one or more user interfaces regarding

the likelihood a person has a gene variant indicative of an atypical event. In particular, the clarified process now recites the step of "determining a first risk of damage to the person, the first risk of damage being associated with administering to the person the dosage of the clinical agent as indicated by the clinician." The clarified process also recites the step of "determining a second risk of damage to the person, the second risk of damage being associated with the damage caused to the person by not administering the dosage of the clinical agent." The clarified process also recites the step of "utilizing the first risk of damage and second risk of damage determinations to generate an output including an automated clinical response containing suggestions for clinical actions to be taken by the clinician." The clarifier process also recites "displaying a third user interface to the clinician, the user interface configured to display the output regarding the generated automated clinical response." The support for these amendments can be found in the specification at paragraphs [0053]-[0055] and FIG. 5. Advantageously, this process allows a clinician to incorporate the available genetic information of a person into the clinical decision making process and weigh the risk of damage to the patient caused by administering a particular clinical agent versus the risk of damage to the patient caused by a particular condition or disease.

By way of contrast with the invention of claims 1, 8 and 15 the Ichikawa reference describes a method of genetic screening where a particular single nucleotide polymorphism may be used to disclose severe side effects or proper dosage for a patient. *See generally, Ichikawa* at p. 523. The Ichikawa reference describes that a patient with an autosomal recessive trait for thiopurine S-methyl transferase (TMPT) deficiency may experience marked leucopenia when treated with immunosuppressants including azathioprine. *Id.* Applicants respectfully submit that the Ichikawa reference fails to teach or suggest features of claim 1, 8 and

15. For instance, the Ichikawa reference fails to teach or suggest determining a first risk of damage to a patient where the first risk of damage is associated with administering to the person the dosage of the clinical agent as indicated by the clinician and determining a second risk of damage to the person that is associated with the damage caused to the person by not administering the dosage of the clinical agent. The Ichikawa reference does not mention a computerized method of weighing the risks of administering versus not administering a particular agent and generating a automated clinical response containing suggestions for clinical actions to be taken by the clinician based on the different risks to the patient.

Applicants respectfully submit that the Reinhoff reference also fails to teach or suggest determining a first risk of damage to a patient where the first risk of damage is associated with administering to the person the dosage of the clinical agent as indicated by the clinician and determining a second risk of damage to the person that is associated with the damage caused to the person by not administering the dosage of the clinical agent. Rather, the Reinhoff reference discloses a computer program product that allows for comparing an individual's polymorphic profile with a plurality of polymorphic profiles to assist in performing clinical trials by ascertaining whether a particular nucleic acid variation affects the efficacy of a pharmaceutical. *Reinhoff.* at ¶¶ [0011]-[0014]. The Reinfhoff reference is silent on computerized method of weighing the risks of administering versus not administering a particular agent and generating a automated clinical response containing suggestions for clinical actions to be taken by the clinician based on the different risks to the patient. Accordingly, Applicants submit that the Ichikawa reference in view of the Reinhoff reference fails to teach or suggest all the limitations of the independent claims 1, 8 and 15.

The Fey reference describes a centralized health screening and management system. *See Fey* at [0020]. In Fey, data and test results are transmitted to a centralized data management system for analysis and storage in a manner that is accessible for report generation and aggregate information analysis. *Id.* The Fey reference does not disclose, determining a first risk of damage to a patient where the first risk of damage is associated with administering to the person the dosage of the clinical agent as indicated by the clinician and determining a second risk of damage to the person that is associated with the damage caused to the person by not administering the dosage of the clinical agent, as described in the invention of claims 1, 8 and 15.

Additionally, Fey is silent on, utilizing the first risk of damage and second risk of damage determinations to generate an output including an automated clinical response containing suggestions for clinical actions to be taken by the clinician. The Fey reference merely discusses storing health data in a manner that is accessible. Accordingly, Applicants submit that the Ichikawa reference in view of the Reinhoff reference and further in view of the Fey reference, fails to teach or suggest all the limitations of the independent claims 1, 8 and 15.

The Fiedotin reference describes a method for providing physicians access to current health care industry information including formulary data, and clinical and practice management information at the point of care on a handheld electronic device. *See Fiedotin* at Abstract. In Fiedotin, health care data is compiled from various sources such as clinical databases, the internet. *Id.* at col. 9 lines 27-29. The health care data includes information such as dosing, co-payment, drug pricing, drug-drug reaction and adverse reaction information. *Id.* at lines 30-35. Nowhere does Fiedotin mention, determining a first risk of damage to a patient where the first risk of damage is associated with administering to the person the dosage of the clinical agent as indicated by the clinician and determining a second risk of damage to the person

that is associated with the damage caused to the person by not administering the dosage of the clinical agent, as described in the invention of claims 1, 8 and 15. Furthermore, Fiedotin is silent on utilizing the first risk of damage and second risk of damage determinations to generate an output including an automated clinical response containing suggestions for clinical actions to be taken by the clinician. Rather, Fiedotin merely describes a method for distributing general medical information stored on a computer system to a physician via a handheld computing device. Accordingly, Applicants submit that the Ichikawa reference in view of the Reinhoff reference and further in view of the Fey and Fiedotin references, fails to teach or suggest all the limitations of the independent claims 1, 8 and 15.

In Hogan, an assay for detecting two or more genetic markers is provided, and based on the results, an operative course of action is selected. See Hogan at [0007]-[0009]. Nowhere does Hogan mention, determining a first risk of damage to a patient where the first risk of damage is associated with administering to the person the dosage of the clinical agent as indicated by the clinician and determining a second risk of damage to the person that is associated with the damage caused to the person by not administering the dosage of the clinical agent, as described in the invention of claims 1, 8 and 15. Furthermore, Hogan is silent on utilizing the first risk of damage and second risk of damage determinations to generate an output including an automated clinical response containing suggestions for clinical actions to be taken by the clinician. Accordingly, Applicants submit that the Ichikawa reference in view of the Reinhoff reference and further in view of the Fey, Fiedotin and Hogan references, fails to teach or suggest all the limitations of the independent claims 1, 8 and 15.

As the Ichikawa reference in view of the Reinhoff reference and further in view of the Fey, Fiedotin and Hogan references fails to teach or suggest all the limitations of the

independent claims 1, 8 and 15, a *prima facie* case of obviousness has not been made for independent claims 1, 8 and 15 with respect to these references. Accordingly, Applicants respectfully request withdrawal of the 35 U.S.C. § 103(a) rejection of these claims. Further, as claims 5-7, 10, 12-14, 17 and 19-21 depend directly or indirectly from amended independent claims 1, 8 and 15, Applicants request withdrawal of the rejection of these claims as well.

CONCLUSION

For at least the reasons stated above, claims 1, 3, 5- 8, 10, 12-15, 17, and 19-23 are now in condition for allowance. Applicants respectfully request withdrawal of the pending rejections and allowance of the claims. If any issues remain that would prevent issuance of this application, the Examiner is urged to contact the undersigned – 816-474-6550 or ajthompson@shb.com (such communication via email is herein expressly granted) – to resolve the same. It is believed that no fee is due, however, the Commissioner is hereby authorized to charge any amount required to Deposit Account No. 19-2112.

Respectfully submitted,

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